I. Remarks

Status of Claims

Claims 25-48 are currently pending.

II. *Rejections of claims 25-47 under 35 U.S.C. § 101*

Claims 25-47 have been rejected under 35 U.S.C. § 101 as allegedly not supported by "either a specific and substantial asserted utility, or a well-established utility." *See*, Paper No. 20060720, page 2. More specifically, the Patent Office alleges that "none of the asserted utilities satisfy all three prongs" [i.e. credible, specific, and substantial] required under 35 USC 101 to establish a specific, substantial or well-established utility. *See*, Paper No. 20060720, page 5. Applicants respectfully disagree and traverse this rejection.

As a preliminary matter, Applicants submit that the instant specification does assert a utility that meets the three prong test, namely that an asserted utility is credible, specific, and substantial, as required under 35 USC § 101. In fact, the Patent Office acknowledges that "[t]he disclosure recites ... [HHPEN62] 'may' be involved in neuronal survival. This asserted utility is credible but is not specific or substantial." *See*, Paper No. 20060720, page 5. Accordingly, Applicants respectfully submit that rejection of claims 25-47 is based on an alleged failure to disclose a specific and substantial utility, although the utilities disclosed in the specification are credible. Applicants respectfully disagree and traverse the Patent Office's rejection of claims 25-47 under U.S.C. § 101 for asserting a credible utility that allegedly is neither specific nor substantial.

In support of the Patent Office's assertion that the utilities disclosed in the instant specification are neither specific nor substantial, albeit, credible, the Patent Office states "the polypeptide to which the antibody binds is not associated with a specific disease and there is no evidence on the record that it is associated with any diseases." Paper No. 20060720, page 3. Similarly, the Patent Office further alleges that "Applicants have not presented evidence that the instant protein (to which the antibody is specific for), has anything to do with neural or neurodegenerative disease or any other disease or condition or that an alternation in this protein has anything to do with any disease or condition." Paper No. 20060720, page 4.

Applicants respectfully disagree with the Patent Office's characterization of the instant specification. The specification states that the protein of the instant invention is involved, *inter alia*, in neuronal and neurodegenerative disorders. *See*, page 85, paragraph 0197 ("polypeptides corresponding to this gene [HHPEN62] would be useful for treating,

preventing, detecting and/or diagnosing neural and neurodegenerative disorders.") Accordingly, Applicants have clearly associated the polypeptide with a specific disease. In support of this assertion, the specification provides a detailed description of the structure and activity of the specified polypeptides, and discloses that the instant invention is primarily expressed in the brain and is located in a chromosomal region (18q22-23), that is well-known in the art as a susceptibility loci for neuronal and neurodegenerative disorders. *See*, page 84, paragraphs 0194-0195. Thus, the instant specification provides clear evidence that the instant protein is involved in neuronal or neurodegenerative disease.

In addition, post-filing date art supports the assertion that the protein of the instant invention is involved in neuronal and neurodegenerative disorders. For example, Applicants respectfully direct the Patent Office's attention to the cloning and identification of carnosinase (CN1) by Tuefel and colleagues several years after the filing date of the instant specification. *See*, **Exhibit A**. Applicants note that CN1 is 100% identical to the HHPEN62 sequence disclosed in the instant specification. *See*, **Exhibit B**. Furthermore, Tuefel and colleagues confirm, as described in the instant specification, that HHPEN62/Carnosinase is specifically expressed in the brain, and that HHPEN62/Carnosinase is useful, *inter alia*, in treating, preventing, detecting and/or diagnosing neural and neurodegenerative disorders. *See*, **Exhibit A**, page 6526, right column, second full paragraph ("All data together suggests constitutive expression of CN1 protein in adult human brain") and page 6531, right column, last sentence ("the identification of the long sought for carnosinase gene and the detailed characterization of the purified recombinant protein provide useful tools to study the biological role of this enzyme in aging and neurodegenerative and psychiatric diseases").

Similarly, Vistoli and colleagues confirm that HHPEN62/Carnosinase is useful, *inter alia*, in treating, preventing, detecting and/or diagnosing neural and neurodegenerative disorders by summarizing the role of HHPEN62/Carnosinase in the neuronal disorder homocarnosinosis, Parkinson's disease, multiple sclerosis, and predicting clinical outcomes following acute stroke. *See*, **Appendix C**, page 3269, right column, first full paragraph.

Thus, the evidence provided in the specification that the protein of the instant invention is involved in, *inter alia*, neuronal and neurodegenerative disorders confirmed by post-filing date art strongly suggests that the asserted association made by Applicants between the instant invention and neuronal and neurodegenerative disorders is specific and substantial.

In conclusion, not only does the instant specification provide a nexus between the structure and activity of the specified polypeptides, the brain-specific expression of the specified polypeptides, and their chromosomal localization to a susceptibility loci for neuronal and neurodegenerative disorders, but also, the assertion that the instant invention is useful, *inter alia*, in treating, preventing, detecting and/or diagnosing neural and neurodegenerative disorders is correct as confirmed by post-filing date articles. Accordingly, Applicants respectfully submit that Applicants' burden under 35 USC 101 to assert a credible, specific, and substantial utility has been met.

Moreover, Applicants respectfully submit that the Patent Office has not met its burden in showing that one of skill in the art would not be convinced that the asserted utilities are not specific and substantial. For example, the Patent Office has not provided any evidence to show that the asserted utility would be considered false by a person of ordinary skill in the art, that the logic underlying the assertion is seriously flawed, or that the facts upon which the assertion of utility is based are inconsistent with the logic underlying the assertion. *See* M.P.E.P. § 2107.02III(A) at 2139-40, and § 2107.02(B) at 2100-40. Indeed, the finding by the Patent Office that the asserted utility is credible would strongly suggest that one of skill in the art would believe that the disclosed utilities of the instant invention are specific and substantial.

In view of the above arguments in combination with the arguments present in Applicants' July 12, 2006 response, Applicants have provided evidence and reasoning which supports the Applicants' assertion of utility. In particular, Applicants have provided evidence that the polypeptides and/or antibodies raised against the polypeptide of the instant application are useful, *inter alia*, in treating, preventing, detecting and/or diagnosing neural and neurodegenerative disorders. Accordingly, Applicants respectfully submit that the rejection of claims 25-47, under 35 U.S.C. § 101 has been obviated. Thus, Applicants respectfully request that the rejection of claims 25-47 be reconsidered and withdrawn.

III. *Rejections of claims 25-47 under 35 U.S.C. § 112*

The Examiner rejected claims 25-47 under 35 U.S.C. § 112, first paragraph because the claimed invention is allegedly "not supported by either a specific and substantial or a well established utility." Paper No. 4202006, page 6. Applicants respectfully disagree and traverse.

Applicants respectfully submit that the Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. §101 rejection is proper." M.P.E.P. § 2107.01(IV) at 2100-36. As discussed above, the claimed invention complies with the utility requirement of 35 U.S.C. § 101. Accordingly, Applicants respectfully request that the rejection of claims 25-47 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

IV. Conclusion

The Applicant respectfully requests that the aforementioned amendments and remarks be entered and made of record in the file history of the instant application. In view of the foregoing remarks, the Applicant believes that the Examiner's concerns have been fully addressed and that this application is in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by the Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: September 8, 2006

Respectfully submitted,

By _____

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